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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,210	12/09/2003	B. Thomas Barker	4002-	4618
7590 07/10/2008 Woodard, Emhardt, Moriarty, McNett & Henry LLP Bank One Center/Tower Suite 3700 111 Monument Circle Indianapolis, IN 46204-5137			EXAMINER	
			SWIGER III, JAMES L	
			ART UNIT	PAPER NUMBER
			3733	
		MAIL DATE	DELIVERY MODE	
		07/10/2008	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/731,210	<b>Applicant(s)</b> BARKER ET AL.
	<b>Examiner</b> JAMES L. SWIGER	<b>Art Unit</b> 3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 March 2008.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 44-52,54-58,70-72 and 74-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 44-52,54-58,70-72 and 74-77 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 12/9/2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "inner crest diameter" of claims 70 and 74 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

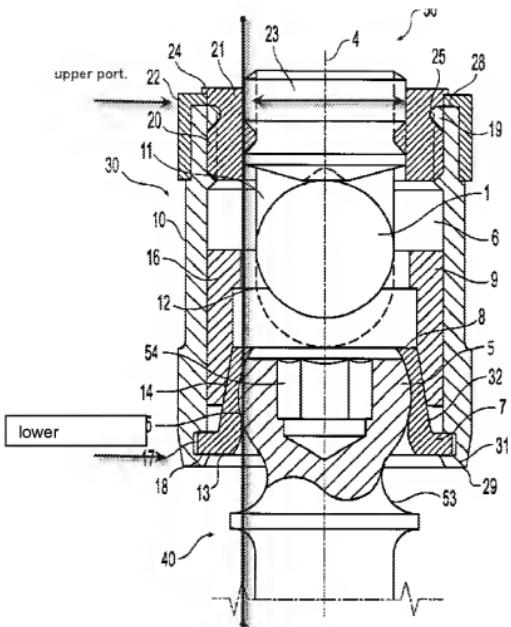
Claims 70-72 and 74-76 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. An "inner crest diameter" is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The claimed upper portion is internally threaded and also has an inner crest diameter, which is not described specifically. Further, the size of this crest diameter is used as a basis for comparison later in the claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 44-47, 49-52, 54-57, 70-72, and 74-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlapfer et al. (US patent 6, 248, 105) in view of Lombardo (US Publication 2001/0001119). Schlapfer et al. disclose a medical implant apparatus comprising a receiver member (30) having a longitudinal axis (4), an upper portion and lower portion (see drawing below).

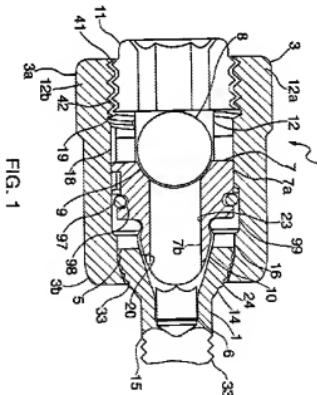


*Fig. 1*

Schlafper also disclose a transverse channel and a longitudinal member occupying this space (1) an interior groove (17) that is substantially perpendicular to the axis, a retaining member (7) that also has an inner and outer dimension and wherein the retaining member occupies the groove (17) and is considered substantially circular and may be considered planar in one perspective, and may be fixed from radial movement depending on how the device is used. Schlafper further comprises a bone anchor having a head (5) that fits within the receiver member, which is considered

substantially between the retaining member (defined at lower portion and between upper portion). The groove communicates with the lower opening the retaining member substantially surrounds a part, or neck of the bone anchor. Also disclosed is a closure member (23) which assists in maintaining a closed or locked position of the apparatus. It is further noted that Schlapfer discloses an inner crest diameter (shown in drawing as double-sided arrow) which further defines a width which is comparatively smaller than a lower portion diameter. Note line drawn in figure. At least a portion of the retaining member may be considered a crown to be part of the head of the bone anchor.

Schlapfer discloses the claimed invention except for the upper opening having internal threading and also a set screw which secures and cooperates with threads and secures the device. Lombardo ( see below)



discloses a medical fixation apparatus that has an upper opening (between 3 and 3a) having internal threading (42) and also a set screw (11) which secures and

cooperates with threads and secures the device. These features help to secure a rod or longitudinal member in place during the placement of the device for more precise level of fixation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Schlapfer et al. having at least the upper opening having internal threading and also a set screw which secures and cooperates with threads and secures the device in view of Lombardo to better secure and set the device during surgery.

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Schlapfer '105 and Lombardo '119 as applied to claim 54 above, and further in view of Farris et al. (US Publication 2003/0004512). The combination of Schlapfer '105 and Lombardo '119 disclose the claimed invention except for reverse angle threads. Farris et al. disclose reverse angle threads (52) and see also par 0079. Reverse angle threads are known in the art and may help the device remain in alignment and prevent splaying. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combo Schlapfer '105 and Lombardo '119 having reverse angle threads as taught by Farris et al. to better secure the device and prevent splaying.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Schlapfer '105 and Lombardo '119 as applied to claim 44 above, and further in view of Nichols (US Patent 6,090,111). The combination discloses the claimed invention except for the split ring. As known in the art to allow for size adjustability and better fit, the split ring is taught and shown by Nichols (42, Col. 4, lines 1-15). it would

have been obvious to one having ordinary skill in the art to create the combination of Schlapfer '105 and Lombardo '119 having the split ring of Nichols to better secure the bone anchor in relation to the securing apparatus.

***Response to Arguments***

Applicant's arguments with respect to claims 44-52, 54-58, 70-72 and 74-77 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is (571)272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L SWIGER/  
Examiner, Art Unit 3733

/Cris L. Rodriguez/  
Supervisory Patent Examiner, Art Unit 3732